In the United States Court of Federal Claims

No. 17-172V

(Filed Under Seal: May 3, 2024)
(Reissued for Publication: May 29, 2024)

RONALD STURDEVANT,	)
Petitioner,	)
v.	)
SECRETARY OF HEALTH AND HUMAN SERVICES,	)
Respondent.	)

William E. Cochran, Jr., Black McLaren Jones Ryland & Griffee, P.C., Memphis, TN, for Petitioner.

Zoë R. Wade, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent. With her on the briefs were Brian M. Boynton, Principal Deputy Assistant Attorney General, Civil Division, as well as C. Salvatore D'Alessio, Director, Heather L. Pearlman, Deputy Director, and Alexis B. Babcock, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

OPINION AND ORDER[1]

LETTOW, Senior Judge.

Pending before the court is respondent's motion for review of Special Master Dorsey's entitlement decision entered on July 19, 2022, finding that petitioner's Bell's Palsy was caused by an influenza ("flu") vaccination. Resp't's Mot. for Review, ECF No. 122. Petitioner, Mr. Ronald Sturdevant, had filed a petition seeking compensation under the National Vaccine Injury Compensation Program on February 6, 2017. Pet., ECF No. 1. Mr. Sturdevant received a flu vaccination on November 3, 2015, and he alleges that this vaccination caused him to suffer Bell's Palsy. Pet. ¶¶ 2-12. On July 19, 2022, the Special Master found that Mr. Sturdevant had "established by preponderant evidence that his flu vaccine caused his Bell's Palsy." *Sturdevant*

[1] In accord with the Rules of the Court of Federal Claims ("RCFC"), App. B ("Vaccine Rules"), Rule 18(b), this opinion and order was initially filed under seal. By rule, the parties had fourteen days within which to propose redactions.

v. Sec'y of Health & Hum. Servs. ("*Entitlement Ruling*"), No. 17-172V, 2022 WL 3369716, at *30 (Fed. Cl. Spec. Mstr. July 19, 2022). This determination rested on both petitioner's medical history and opinions from three expert witnesses: Dr. Gershwin for petitioner, and Drs. Chaudhry and Romberg for respondent. *Id.* at *4-22. The Special Master then issued a damages decision on February 12, 2024. *Sturdevant v. Sec'y of Health & Hum. Servs.*, No. 17-172V, 2024 WL 1045145, at *1 (Fed. Cl. Spec. Mstr. Feb. 12, 2024). On March 13, 2024, respondent moved for review of the Special Master's entitlement decision. Resp't's Mot. for Review; Resp't's Mem. in Supp. of Mot. for Review ("Resp't's Mem."), ECF No. 123. Respondent's motion for review is fully briefed, Pet'r's Resp. to Resp't's Mot. for Review ("Pet'r's Resp."), ECF No. 128, and a hearing was held on April 18, 2024, Review Hr'g Tr. (Apr. 18, 2024), ECF No. 130. The motion is ready for disposition.

BACKGROUND

A. Vaccination and onset of Bell's palsy

The parties agree that Mr. Sturdevant suffered Bell's palsy. "Bell's palsy is characterized by the acute spontaneous onset (72 hours or fewer) of unilateral peripheral facial paresis or palsy in isolation (no other neurologic or systemic signs), for which no specific etiology is uncovered." Resp't's Ex. Q at 1, ECF No. 24-15. Those suffering Bell's palsy "may experience dryness of the eye or mouth, taste disturbance or loss, hyperacusis [(sensitivity to sound)], and sagging of the eyelid or corner of the mouth." Pet'r's Ex. 8 at 2, ECF No. 12-3. "Bell's palsy is characteristically [asymmetric]," Entitlement Hr'g Tr. 252:4-19 (Gershwin), July 13 and 14, 2024, ECF Nos. 74-75[2]; Resp't's Ex. Q at 2, such that the symptoms occur on one side of a person's face. *See*, Resp't's Ex. Q at 6 fig. 5-4. Because "[t]he cause of Bell's palsy is not known and may not be the same in all individuals," Resp't's Ex. Q at 6, "Bell's palsy is a diagnosis of exclusion requiring the careful elimination of other causes of facial paresis or paralysis," Pet'r's Ex. 8 at 2. It is suspected to arise "from facial nerve inflammation and edema. As the facial nerve travels in a narrow canal within the temporal bone, swelling may lead to nerve compression and result in temporary or permanent nerve damage." *Id.* While the etiology of Bell's palsy "is still unclear," Pet'r's Ex. 21 at 1, ECF No. 13-7, "[t]here are several known risk factors" including "obesity, hypertension and chronic hypertension, [and] diabetes," Pet'r's Ex. 8 at 2-3.

Mr. Sturdevant received the flu vaccination in his left upper arm on November 3, 2015. Pet'r's Ex. 40 at 2, ECF No. 34-1. At that time, he had a prior medical history of hypertension, allergic rhinitis, obstructive sleep apnea, diabetes, and obesity. Pet'r's Ex. 3 at 18, ECF No. 7-3. The next day, petitioner began experiencing numbness on the right side of his face. *See id.* Petitioner first reported these issues to his primary care physician, Dr. Depner, on November 5. Mr. Sturdevant visited Dr. Depner three times in November 2015 for issues related to his facial numbness. Dr. Depner noted petitioner exhibited "fairly classic Bell's palsy with paresis in the distribution of the right 7th nerve" and, more specifically, that Mr. Sturdevant had "rather dense

[2] Citations to the entitlement hearing transcript are cited as "Entitlement Hr'g Tr. __:__ (Witness)."

right facial nerve paresis" and was unable to close his right eye fully. *Id.* at 18, 20.[3] During the visit Dr. Depner also examined his neck, noting it was "[n]ormal to inspection[,] [n]ormal to palpation[,] [n]o masses appreciated," and found there was no visible regional swelling in petitioner's lymph nodes. *Id.* at 19. Dr. Depner prescribed Mr. Sturdevant prednisone and Famvir (Famciclovir) and advised him to wear an eye patch over his right eye, massage his face, and abstain from working to avoid further irritating his eyes. *Id.* at 20. Famvir is an antiviral treatment, Entitlement Hr'g Tr. 115:21 to 116:11 (Gershwin), and prednisone is administered orally as an anti-inflammatory and immunosuppressant, *Entitlement Ruling*, 2022 WL 3369716, at *4 n.16.

Mr. Sturdevant returned to Dr. Depner on November 10 and 23. Pet'r's Ex. 3 at 21-26. At both visits, Mr. Sturdevant's neck again appeared "[n]ormal to inspection" and his lymph nodes were not visibly swollen. *Id.* at 22, 25. Dr. Depner noted that petitioner had not "made much improvement with his facial paralysis" and sent him to physical therapy for electrical muscle stimulation and massage. *Id.* at 26.

On December 9, 2015, Mr. Sturdevant attended physical therapy to address the difficulties he was experiencing as a result of his Bell's palsy, namely his limited range of motion on the right side of his face,[4] "hand[-]eye coordination, blurry vision," and difficulty "drinking from a cup or a straw." Pet'r's Ex. 4 at 44-46, ECF No. 7-4. The physical therapist also found Mr. Sturdevant's symptoms to be consistent with Bell's palsy and created a plan for addressing his symptoms over the next eight weeks. *Id.* at 45-46.

During follow up visits with Dr. Depner on December 14, 2015, and May 25, 2016, Mr. Sturdevant showed signs of improvement. Pet'r's Ex. 3 at 27-35. At the May visit, Dr. Depner indicated Mr. Sturdevant was "able to blink" and "drink liquids and drink with a straw" and that "[h]e is near the point of maximum medical improvement." *Id.* at 34. Over a year later, on July 11, 2017, Dr. Depner noted that Mr. Sturdevant's "Bell[']s palsy has improved quite slowly, but is still quite marked." Pet'r's Ex. 26 at 19, ECF No. 15-1. At that visit, Dr. Depner stated petitioner developed Bell's palsy "about a week after he received the flu vaccine" and that "[i]t is conceivable" his ailment was precipitated by the flu vaccine. *Id.*

B. Relevant features of the immune system and facial anatomy

The Special Master's opinion considers various aspects of the body's immune response to a vaccine. Vaccines are designed to stimulate the immune system. Entitlement Hr'g Tr. 15:12-19 (Gershwin). "Once stimulated, the immune system sets off a complex series of innate immune events." Pet'r's Ex. 55 at 2, ECF No. 71-1. The vaccine is processed by "regional cells, by macrophages, the dendritic cells, [and] by other mononuclear cells that [are] rapidly transported to regional lymph nodes." Entitlement Hr'g Tr. 20:10-19 (Gershwin). Additionally,

[3] Dr. Depner's notes include an apparently inadvertent reference to petitioner's left eye when describing his symptoms.

[4] Petitioner's physical therapy notes mistakenly refer to mobility issues as occurring on the left side of plaintiff's face after noting he has right sided Bell's palsy.

"inflammatory mediators including . . . cytokines" are released, Pet'r's Ex. 55 at 2, and "travel in the blood" and through the lymphatic system. Entitlement Hr'g Tr. 20:12-19 (Gershwin). This cytokine release can be "systemic" and go "all over the body." *Id.* at 26:14-21 (Gershwin), 236:13-16 (Romberg) (acknowledging that, "in theory," "proinflammatory cytokines [a]re capable of reaching organs remote from the injection site"). The flu vaccine prompts an innate inflammatory response in lymph nodes, and this response can affect body parts away from the vaccination site. *Id.* at 24:23 to 26:21 (Gershwin). This innate response is essential to developing adaptive immunity days to weeks after vaccination. *See id.* at 16:2 to 17:14 (Gershwin).

The lymphatic system plays an important role in the immune response triggered by a vaccine. It "comprises a network of vessels and nodes that circulate immune cells and provide a site for antigen presentation and immune activation." Resp't's Ex. MM at 1, ECF No. 58-1. The lymphatic system "clears fluid, macromolecules (including proteins), particulates (including infectious materials such as bacteria) and small molecules . . . from the peripheral tissues into the systemic circulation." *Id.* After entering the lymph system through lymphatic capillaries, these fluids, particulates, and small molecules flow through "progressively larger pre-collecting and collecting lymphatic vessels, lymph nodes and post-nodal (efferent) lymphatic vessels each segmented frequently by semilunar valves to facilitate unidirectional flow." *Id.* Lymph nodes exist throughout the human body, including in the shoulder, *id.* at 2 fig. 1, and in the face's parotid gland through which the seventh cranial nerve passes, Resp't's Ex. DD at 3; Entitlement Hr'g Tr. 160:24 to 161:4 (Chaudhry). There are no lymph nodes within the fallopian canal through which the facial nerve passes. Review Hr'g Tr. 5:11-20. There is also no lymphatic pathway directly connecting the left shoulder with the right side of the face. Entitlement Hr'g Tr: 219:8-14 (Romberg). A vaccination administered in the left shoulder would cause vaccine components or inflammatory products first to enter axillary lymph nodes in the left shoulder and travel toward the heart and ultimately be drained through the thoracic lymph duct into the circulatory system. Resp't's Ex. MM at 1-3; Entitlement Hr'g Tr. 219:7 to 220:18 (Romberg). The vaccine components and inflammatory products could then be circulated everywhere in the body through the blood. Entitlement Hr'g Tr. 219:7 to 220:18 (Romberg).

C. Expert testimony considered by the Special Master

The Special Master considered opinions from three expert witnesses. Dr. Gershwin opined that the flu vaccination administered to Mr. Sturdevant triggered an immune response that "included a localized inflammatory reaction within the facial nerve, similar to the mechanisms associated with viral infection-induced Bell's palsy." Pet'r's Ex. 6 at 2, ECF No. 12-1. More specifically, Dr. Gershwin testified that a local inflammatory response in Mr. Sturdevant's left shoulder would occur within hours of vaccination. Entitlement Hr'g Tr. 49:21 to 50:21 (Gershwin) (relying on Pet'r's Exs. 55 (Hervé) and 28 (Chatziandreou)). Subsequently, macrophages and other cells in the regional lymph nodes of the shoulder are activated, and cytokines are released, trafficked in the circulatory system, and "activate lymphocytes throughout the body." *Id.* at 52:16 to 54:2 (Gershwin). Accordingly, Dr. Gershwin opined that vaccine components and immune cells and proteins would reach "lymph nodes in his facial area, particularly in his parotid gland and adjacent regions," and cause inflammation within the facial nerve and nearby areas after travelling through both the circulatory and the lymphatic system. *Id.* at 20:12-19, 42:15-22, 49:19 to 54:20 (Gershwin). This inflammation would compress the

facial nerve and cause paralysis. *Id.* at 42:15 to 43:1 (Gershwin). These mechanisms are similar to viral infection-induced Bell's palsy insofar as both involve inflammation and compression of the facial nerve. Pet'r's Ex. 6 at 2-3.

Dr. Chaudhry argued Dr. Gershwin's theory failed to account for the short timeline between petitioner's vaccination and the onset of his symptoms and contended Mr. Sturdevant's Bell's palsy was instead caused by a reactivation of herpes virus or ischemia. Resp't's Ex. A at 4-6, ECF No. 22-1. Dr. Chaudhry opined that "[d]eveloping symptoms within twenty[-]four hours of receiving a vaccine, as is claimed for Mr. Sturdevant, is too short an interval" for an adaptive immune reaction to an antigen. *Id.* at 6; *see* Pet'r's Ex. 27 at 1, ECF No. 25-1. Moreover, none of the sources Dr. Gershwin relied upon establish an association between influenza vaccination and Bell's palsy. Resp't's Ex. A at 5-6. Indeed, six studies Dr. Chaudhry identified indicate "the lack of causative relationship between seasonal flu vaccine and Bell's palsy." *Id.*

Dr. Chaudhry proposed two alternative causes of Bell's palsy. Resp't's Ex. A at 4-5. First, the viral hypothesis posits that Bell's palsy is caused by viral reactivation. *See id.*[5] On this theory, after the herpes virus enters the respiratory tract through a person's nose and throat, it "travels up the axons of sensory nerves to take residence in the sensory ganglion" near the seventh facial nerve. Pet'r's Ex. 16 at 11, ECF No. 13-2; Resp't's Ex. Q at 4 fig. 5-3. Subsequently, "[w]ith reactivation . . . the virus replicates within the ganglion cells, then travels down the axon to cause local disease in the nerve and nerve endings." Pet'r's Ex. 16 at 11. Bell's palsy is one outcome of the reactivation of herpes viruses in the geniculate ganglion. Resp't's Ex. A at 4. Second, "[i]schemia is thought to be another potential etiology." *Id.* at 5; *see also* Entitlement Hr'g Tr. 90:20 to 91:9 (Chaudhry) (explaining that "ischemia[,] which just means reduced blood flow," is thought to cause Bell's palsy when reduced circulation to a nerve "caus[es] malfunction or dysfunction of the nerve"). While Dr. Chaudhry did not opine that one of these was the cause of Mr. Sturdevant's Bell's palsy, he concluded that "[e]ither one or both could be playing a part." Entitlement Hr'g Tr. 170:5-24 (Chaudhry).

At the Special Master's request, both experts supplemented their reports to address whether "the onset of Bell's palsy within 24 hours of receiving the influenza vaccine was too rapid to be caused by the vaccine." Pet'r's Ex. 27 at 1; *see* Order of Feb. 16, 2018, ECF No. 23; Resp't's Ex. R, ECF No. 26-1. Dr. Gershwin distinguished between innate and adaptive immune responses and opined that the former explained the rapid onset of Mr. Sturdevant's symptoms. Pet'r's Ex. 27 at 1. Innate responses are nonspecific and occur first while adaptive responses are targeted and arise after the innate response. *See* Resp't's Ex. R at 1. Dr. Gershwin discussed a study "provid[ing] evidence of significant activation [of the immune system] within hours" after vaccination. Pet'r's Ex. 27 at 1. Dr. Gershwin posited that the vaccination triggered a rapid inflammatory response, including swelling in local lymph nodes, that then produced the

[5] Dr. Chaudry discussed reactivation of either herpes simplex virus or varicella-zoster virus, another herpes virus that causes chickenpox and shingles. Resp't's Ex. A at 3; *see also* Ctrs. for Disease Control & Prevention, *Chickenpox (Varicella): For Healthcare Professionals*, https://www.cdc.gov/chickenpox/hcp/index.html (Oct. 21, 2022). For simplicity this court refers to both collectively as "herpes virus(es)."

"tissue-specific innate response" in Mr. Sturdevant's facial nerve. *Id*. Dr. Chaudhry focused on the circuitous pathway between Mr. Sturdevant's injection site and his seventh facial nerve. Because Mr. Sturdevant received the vaccine in his left arm, "the [lymph nodes] affected would be the axillary [lymph nodes], not near the facial nerve, and certainly, not just on the right side." Resp't's Ex. R at 1. While Dr. Chaudhry acknowledged that "part of the seventh nerve goes through the parotid gland," Entitlement Hr'g Tr. 179:23 to 180:4 (Chaudhry), he contended that Dr. Gershwin's explanation fails to explain how a vaccination in the shoulder would trigger an innate immune response in and around Mr. Sturdevant's seventh facial nerve. Resp't's Ex. R. at 1.

The experts also focused on whether reactions in the lymphatic system could provide an explanation for how the flu vaccination could cause Bell's palsy. Dr. Gershwin explained that, because "the lymphatic system is not a stationary system," vaccination in the shoulder can cause swelling in lymph nodes in other parts of the body. Pet'r's Ex. 30 at 1, ECF No. 27-1. Dr. Romberg authored the government's responsive report and explained that innate immune responses occur in lymph nodes and can be small and cause only local symptoms or, rarely, can be excessive and cause systemic symptoms. Resp't's Ex. S at 3, ECF No. 29-1. Accordingly, he interpreted Dr. Gershwin's theory to rely on an excessive innate response that caused symptoms in Mr. Sturdevant's facial nerves, away from the site of his inoculation. *See id.* Dr. Romberg acknowledged that "[t]here are lymph nodes in and around the parotid gland." Entitlement Hr'g Tr. 234:22 to 235:5 (Romberg); *see also* Resp't's Ex. S at 3 (explaining the pathway from petitioner's shoulder to nodes around the parotid gland would be indirect because "gravity drains deltoid lymphatics down to axillary lymph nodes" then into the circulatory system, "not up into the skull," and "arterial blood supply to and venous blood return from the deltoid is not shared with either cranial nerve"). But, after reviewing the record, Dr. Romberg found "*no* evidence of injection site nor systemic inflammation in the 30 days after Mr. Sturdevant received his season[al] influenza" vaccine. Resp't's Ex. S at 3 (noting the lack of evidence of "visible induration" or other indications of "widely disseminated disease" such as "symmetric not unilateral facial paralysis"). Dr. Romberg stressed that the lack of such evidence undermines Dr. Gershwin's explanation of how vaccine components and immune cells and proteins traveled from the vaccination site in Mr. Sturdevant's left shoulder to his right facial nerve. *Id.*

In reply, Dr. Gershwin clarified that he is "not suggesting that Mr. Sturdevant had an excess[ive] innate response" but instead that "the lymph nodes and the innate immune system that are found surrounding the facial nerve . . . became acutely inflamed, leading directly to compression" due to Mr. Sturdevant's "genetic susceptibility." Pet'r's Ex. 37 at 1-2, ECF No. 33-1. In his final response, Dr. Romberg argued that, had Mr. Sturdevant suffered the systemic response described by Dr. Gershwin, Dr. Romberg would have expected systemic inflammatory symptoms like fever or hypotension. Resp's Ex. LL at 2, ECF No. 40-17. No such symptoms are noted in Mr. Sturdevant's records. *Id.*

STANDARDS FOR REVIEW

This court has jurisdiction to review a special master's decision. 42 U.S.C. § 300aa-12(e)(1)-(2). In reviewing a special master's decision, "[f]indings of fact receive deferential review under an 'arbitrary and capricious' standard, legal conclusions are reviewed de novo under the 'not in accordance with the law' standard, and discretionary rulings are

reviewed for 'abuse of discretion.'" *W.J. by R.J. v. Sec'y of Health & Hum. Servs.*, 93 F.4th 1228, 1234-35 (Fed. Cir. 2024) (quoting *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)). Under this standard, the court "cannot 'substitute its judgment for that of the special master merely because it might have reached a different conclusion.'" *Simeone v. Sec'y of Health & Hum. Servs.*, 167 Fed. Cl. 389, 393 (2023) (quoting *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009)). Nor can it "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). Accordingly, "[r]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences[,] and articulated a rational basis for the decision." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1381 (Fed. Cir. 2021) (quoting *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000)).

This is an off-table case because petitioner does not contend that he suffered an injury listed on the Vaccine Injury Table, which links vaccines with corresponding injuries and time periods in which the first symptom occurs after vaccination. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1354 (Fed. Cir. 2019); 42 C.F.R. § 100.3(a); Pet. ¶¶ 2, 4, 12. Accordingly, petitioner must demonstrate the vaccine caused his injury under the three *Althen* prongs. *Boatmon*, 941 F.3d at 1354-55. That is, petitioner must establish by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010)). Once a petitioner does so, "he or she is entitled to recover unless the government shows 'by a preponderance of evidence[] that the injury was in fact caused by factors unrelated to the vaccine.'" *Id.* at 1355 (quoting *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).

"[E]vidence used to satisfy one of the *Althen* prongs may overlap with and be used to satisfy another prong." *Druery v. Sec'y of Health & Hum. Servs.*, 169 Fed. Cl. 557, 580 (2024). Moreover, a petitioner's medical causal theory "need only be 'legally probable, not medically or scientifically certain.'" *Moberly*, 592 F.3d at 1322 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 548-49 (Fed. Cir. 1994)). This standard reflects the fact that Congress set up a system in which "close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280; *see also Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009) (explaining that, to recover under the Vaccine Act, a petitioner need not provide conclusive evidence in the medical literature, epidemiological studies, or general acceptance in the scientific or medical community).

ANALYSIS

The government challenges the Special Master's ruling that petitioner has set forth both "a sound and reliable medical theory to explain how the flu vaccine can cause Bell's palsy" under *Althen* prong one and "preponderant evidence of a logical sequence of cause and effect showing that his vaccination was the cause of his Bell's palsy" under *Althen* prong two. *Entitlement Ruling*, 2022 WL 3369716, at *26, *28; Resp't's Mem. at 8-16.

A. Sound and reliable causal theory ruling

Regarding petitioner's "sound and reliable" causal theory, the Special Master made four findings. First, the Special Master found "that the innate immune response is initiated after vaccination is well-described in the medical literature and acknowledged by all experts." *Entitlement Ruling*, 2022 WL 3369716, at *27. She noted that Drs. Gershwin and Romberg "agreed that cytokines are produced within minutes to hours after vaccination and produce inflammation." *Id*. And, while Drs. Gershwin and Romberg disagreed about which lymph nodes would be involved, they agreed the innate response occurs in lymph nodes, and Dr. Romberg did not disagree that a local response to a vaccine could travel and produce a response in the facial nerves. *Id.*

Second, the Special Master concluded that "the experts all agree that herpes virus has been suspected to cause Bell's palsy," specifically by inflammation and compression of the seventh cranial nerve. *Entitlement Ruling*, 2022 WL 3369716, at *27. Because these features are shared by "the mechanism proposed by Dr. Gershwin," the Special Master concluded that mechanism "is recognized and accepted as it relates to a viral infection." *Id.*

Third, medical literature indicates the anatomy of the facial nerve and fallopian canal plays a causal role in Bell's palsy. *Entitlement Ruling*, 2022 WL 3369716, at *27. Specifically, because the narrow fallopian canal leaves little room for the nerve to expand, inflammation of the nerve is thought to cause "compression resulting in paralysis." *Id.* (quoting Resp't's Ex. Q at 5).

Fourth, the Special Master relied on studies cited by Dr. Gershwin that "discussed the flu vaccine as a cause of Bell's palsy":

> Zhou et al. concluded there "may be a signal of possible association between [flu] vaccines and an increased risk of Bell's palsy." Pet. Ex. 21 at 5. Kamath et al. found "the likelihood of reporting facial paralysis following [flu] vaccination [was] higher compared with other vaccines." Pet. Ex. 47 at 4. Bardage et al. found "a significantly increased risk for Bell's palsy" in "those vaccinated in the early phase of the vaccination campaign (≤ 45 days), when high risk groups predominated." Pet. Ex. 35 at 4. And Huang et al. concluded "[t]here was an increased risk for Bell's palsy in the interval 0-42 days after vaccination." Pet. Ex. 54 at 3.

Entitlement Ruling, 2022 WL 3369716, at *28. The Special Master also noted that two of these articles, those by Zhou and Kamath, "hypothesized an immune inflammatory response mechanism to be at play." *Id.*

The government challenges the anatomical and immunological basis of the Special Master's ruling, as well as her reliance on an analogy to the causal mechanism in herpes virus-induced Bell's palsy and on studies cited by petitioner's experts.

1. The anatomical and immunological basis of the Special Master's causal theory.

The government argues that the Special Master erred by "credit[ing] a causal theory that is anatomically and immunologically unsound." Resp't's Mem. at 12. The government targets the Special Master's decision to credit two aspects of Dr. Gershwin's theory of the lymph system's causal role. First, the government contends that Dr. Gershwin's "theory that inflammatory compounds disseminate throughout the entire lymphatic system . . . [is] verifiably unsound, both anatomically and immunologically." *Id.* at 14. Instead, the government maintains that "the only manner for innate immune compounds produced at the site of injection to reach the right cranial nerve would be for those compounds to exceed the local environment at petitioner's left deltoid and enter arterial circulation." *Id.* at 13. But the government reads "petitioner's causal theory [to] invoke[] the lymphatic system, not the circulatory system." *Id.* Nonetheless, had innate compounds taken such a path they would have left systemic inflammatory symptoms—such as fever, mayalgia, headache, and hypotension—and no such symptoms were detected in petitioner. *Id.* at 11, 13.

Second, the government maintains that Dr. Gershwin's opinion "that lymph nodes reside within the fallopian canal and can cause compression of the facial nerve" is "verifiably unsound, both anatomically and immunologically" because there are no lymph nodes within the fallopian canal. Resp't's Mem. at 12, 14; Review Hr'g Tr. 5:11 to 6:8 (explaining that compression of the facial nerve would be caused only by swelling within the fallopian canal, not in the parotid gland or soft tissue outside the canal).

Petitioner clarifies that Dr. Gershwin's causal theory relied on both the circulatory and lymphatic systems to explain how innate immune compounds traveled from the injection site to Mr. Sturdevant's face. Pet'r's Resp. at 11, 15. As the Special Master indicated, Drs. Gershwin and Romberg agreed that "a local response initiated by a vaccine could travel and produce a response in the cranial nerves." *Id.* at 14-15 (quoting *Entitlement Ruling*, 2022 WL 3369716, at *27).

Petitioner also explains that the causal theory the Special Master adopted "involve[s] inflammation of lymph nodes within and around the parotid gland" rather than nodes within the fallopian canal. Pet'r's Resp. at 10. Again, petitioner emphasizes the agreement amongst the experts. Dr. Romberg agrees that there are lymph nodes within and around the parotid gland, and Dr. Chaudhry agrees that part of the facial nerve passes through the parotid gland. *Id.* at 10-11 (citing Entitlement Hr'g Tr. 235:2-5 (Romberg) and 179:23-25 (Chaudhry), respectively). Where the experts disagree, petitioner contends the "Special Maser did exactly what she was supposed to do . . . She examined all the medical records, the medical literature, the expert reports and testimony, and she was persuaded by Mr. Sturdevant's expert." Review Hr'g Tr. 21:8-15.

The causal theory adopted by the Special Master is based upon an understanding of anatomy and immunology that is well-supported and shared by the experts in this case. The adopted causal theory does not contemplate that vaccine components and immune compounds traveled from petitioner's shoulder to his face without ever leaving the lymphatic system. Instead, the Special Master relied upon a causal theory incorporating both the lymphatic and the circulatory system. The Special Master found that cytokines that are "produced within minutes

to hours after vaccination and produce inflammation" could travel from lymph nodes at the injection site to the facial nerves based on elements of both Dr. Gershwin and Dr. Romberg's testimony. *Entitlement Ruling*, 2022 WL 3369716, at *27. Indeed, the Special Master relies on Dr. Romberg's testimony that vaccine components and inflammatory mediators would need to enter the circulatory system before reaching the facial nerves. *Id.*[6]

The Special Master also did not find that there are lymph nodes within the fallopian canal, and the causal theory she adopted does not rely on such a finding. Instead, the Special Master's causal theory recognized inflammatory mediators could be transported to "vascularized tissues including facial nerves" as well as lymph nodes in and around the parotid gland. *Entitlement Ruling*, 2022 WL 3369716, at *27 (quoting Resp't's Ex. LL at 2). Neither party's immunology expert disputes that there are lymph nodes within the parotid gland. Entitlement Hr'g Tr. 234:22 to 235:5 (Romberg) ("There are lymph nodes in and around the parotid gland."), 248:23 to 249:16 (Gershwin) (testifying that lymph nodes have long been understood to be located around the parotid gland). Similarly, both Dr. Chaudhry and Dr. Gershwin testified that the facial nerve passes through the parotid gland. *Id.* at 179:23 to 180:4 (Chaudhry) (testifying that "part of the seventh nerve goes through the parotid gland"), 248:23 to 249:16 (Gershwin) ("[T]he facial nerve goes right through that area of the face, of the parotid gland."). In finding petitioner's clinical course was consistent with the proposed causal mechanism, the Special Master stated that "the lymph nodes and the innate immune system that are found surrounding the facial nerve" and within the fallopian canal particularly, "became acutely inflamed, leading directly to compression." *Entitlement Ruling* at *29 (quoting Pet'r's Ex. 37 at 2). Put differently, both lymph nodes in the area surrounding the fallopian canal and components of the innate immune system found within the fallopian canal became inflamed. The innate immune system includes inflammatory mediators that travel in the blood. Resp't's Ex. LL at 2; Pet'r's Ex. 55 at 2, 3, 4 fig. 2 (describing how resident immune cells at the vaccination site recruit "blood-born" cells that then cause the release of "mediators and products of inflammation" that may "spill into the circulation and can affect other body systems causing systemic side-effects"). The causal theory the Special Master adopted logically explains how inflammatory mediators can travel through the circulatory system not only to the parotid gland and the area surrounding the facial nerve but also to the part of the nerve within the fallopian canal.

The Special Master's causal theory did not require that immune compounds traveled between the injection site and petitioner's face solely via the lymphatic system, nor did it rest on lymph nodes existing within the fallopian canal. Accordingly, the causal theory she adopted is consistent with the accepted understanding of human anatomy and immunology and is supported by the expert testimony before her.

2. Herpes virus-induced Bell's palsy as an analogous causal mechanism.

The government also challenges "the Special Master's reliance on the causal mechanism involved in [h]erpes virus-induced Bell's palsy as a surrogate in this case" because herpes simplex virus "resides in the facial nerve and reactivation leads to local inflammation, whereas

[6] Respondent's arguments concerning the lack of evidence of a systemic immune response are discussed *infra* 13-14.

petitioner's theory here is predicated on a focal inflammatory response at a remote location." Resp't's Mem. at 14.

Petitioner argues the analogous feature shared by the causal mechanism in herpes virus-induced Bell's palsy and that adopted by the Special Master is that both rely on inflammation leading to compression and then paralysis of the seventh cranial nerve. Pet'r's Resp. at 16. Accordingly, the Special Master's reliance on the analogy is not undermined by the fact that herpes virus-induced Bell's palsy involves local inflammation caused by local reactivation while petitioner's causal mechanism involves a systemic immune response that transports inflammatory mediators from petitioner's shoulder to his face. *See id.*

The Special Master did not err in concluding that the causal mechanism in Mr. Sturdevant's case was analogous to herpes virus-induced Bell's palsy. The Special Master found that "the mechanism proposed by Dr. Gershwin is recognized and accepted" because it is relevantly analogous to the mechanism thought to be at play in "Bell's palsy cases caused by reactivation of herpes." *Entitlement Ruling*, 2022 WL 3369716, at *27. The Special Master pointed to agreement among the experts regarding inflammation's key role in causing Bell's palsy. Dr. Chaudhry testified that "the herpes mechanism involves inflammation of the seventh cranial nerve." *Id.*; *see* Entitlement Hr'g Tr. 152:17-22. And Dr. Romberg opined that "with reactivation of herpes, inflammation occurs and causes the nerve to swell." *Entitlement Ruling*, 2022 WL 3369716, at *27; *see* Entitlement Hr'g Tr. 231:13-21. The mechanism proposed by Dr. Gershwin and accepted by the Special Master is relevantly the same "in that both lead to inflammation and compression of the seventh cranial nerve." *Entitlement Ruling*, 2022 WL 3369716, at *27. This finding is rationally based on the experts' testimony. Respondent's complaint that the causal mechanism at issue here is more attenuated than that in herpes virus-induced Bell's palsy is merely another way of lodging the challenge addressed *supra* 8-10. Accordingly, the Special Master did not err in finding that Dr. Gershwin's causal mechanism "is recognized and accepted as it relates to a viral infection." *Id.*

3. Studies discussing flu vaccine as a cause of Bell's palsy.

The government next contends "the Special Master mischaracterized studies that have investigated a potential causal connection between the flu vaccine and Bell's palsy" when she stated: "'While the authors of these studies did not reach conclusions as to the pathogenesis of Bell's palsy, some hypothesized an immune inflammatory response mechanism to be at play.'" Resp't's Mem. at 14 (quoting *Entitlement Ruling*, 2022 WL 3369716, at *28). Respondent specifically targets the Special Master's discussion of the studies authored by Zhou, Pet'r's Ex. 21, and Kamath, Pet'r's Ex. 47, ECF No. 56-1. Expanding on a study identifying that the use of "intranasal inactivated influenza vaccine" "increased [the] risk for Bell's palsy," the Zhou study investigated whether "parenteral inactivated influenza vaccines . . . also increase the risk for Bell's palsy." Pet'r's Ex. 21 at 1. Respondent focuses on the fact that the Zhou article studied an adaptive, not innate, immune response and on an acknowledgment in the Zhou article that "there is no current evidence that support[s] th[e] theory" that "an immune inflammatory response mechanism [is] at play." Resp't's Mem. at 14 (first quoting Pet'r's Ex. 21 at 5, then quoting *Entitlement Ruling*, 2022 WL 3369716, at *28). The article by Kamath examined "whether the facial paralysis reporting rate is higher in those who received influenza vaccination compared with those who received other vaccines." Pet'r's Ex. 47 at 1. Respondent notes the

Kamath article "merely noted a temporal relationship, stating 'The appearance of Bell's palsy after the vaccination supports the immunological hypothesis.'" Resp't's Mem. at 14 (quoting Pet'r's Ex. 47 at 4).

Petitioner responds that the Special Master properly evaluated the studies investigating the flu vaccine as a cause of Bell's palsy. Petitioner focused on the fact that the Zhou article stated that "[i]t is known that certain influenza vaccines may be associated with Guillain-Barré syndrome, . . . possibly th[r]ough an immune response mechanism" and acknowledged the "theoretical[] possib[ility] that influenza vaccines may trigger Bell's palsy through a similar mechanism." Pet'r's Ex. 21 (cited in Pet'r's Resp. at 16). Moreover, the Kamath article states that "[t]he appearance of Bell's palsy after the vaccination supports the immunological hypothesis; intranasal immunization may be more commonly associated, as it stimulates both mucosal and systemic immune responses compared to parenteral administration of influenza vaccine." Pet'r's Ex. 47 at 4. According to petitioner, this "implicate[s] a systemic immune response" that "by inference includes an innate inflammatory response." Pet'r's Resp. at 16.

The Special Master accurately characterized these studies in finding that "studies have discussed the flu vaccine as a cause of Bell's palsy" and that "[w]hile the authors of these studies did not reach any conclusions as to the pathogenesis of Bell's palsy, some hypothesized an immune inflammatory response mechanism to be at play." *Entitlement Ruling*, 2022 WL 3369716, at *28. The Special Master expressly acknowledged the authors of the studies she discussed did not draw any conclusions about how flu vaccination influences the risk of Bell's palsy. *Id.* Instead, these studies demonstrate that scientific literature provides at least some support for petitioner's causal theory insofar as they recognize both a relationship between influenza vaccination and incidence of Bell's palsy and that a causal mechanism similar to that proposed by petitioner may be at play.

The Zhou article states that "[i]t has been hypothesized that an immune-mediated segmental demyelination may be involved" in the "etiology and the pathogenesis of Bell's palsy." Pet'r's Ex. 21 at 5. This hypothesis extrapolates from "know[ledge] that certain influenza vaccines may be associated with Guillain-Barré syndrome, a demyelinating disease, possibly th[r]ough an immune response mechanism." *Id.* Indeed, in the key points section, the article's authors state that they "found 154 verifiable Bell's palsy reports after influenza vaccines," that "[t]hese reports may be a signal of possible association between influenza vaccines and an increased risk of Bell's palsy," and that "[a] population-based controlled study is needed to determine whether this association is causal or coincidental." *Id.*

The Kamath article concluded that "[t]he risk of reporting of facial paralysis following influenza vaccination seems to be higher compared with that following the administration of other vaccines" but cautioned that the "study findings need to be explored in well-designed prospective pharmacoepidemiologic studies" due to limitations in the database the authors used. Pet'r's Ex. 47 at 6. The authors also found that "[t]he appearance of Bell's palsy after the vaccination supports the immunological hypothesis; intranasal immunization may be more commonly associated, as it stimulates both mucosal and systemic immune responses compared to parenteral administration of influenza vaccine." *Id.* at 4. Accordingly, this study suggests that the appearance of Bell's palsy after vaccination supports the immunological hypothesis though the correlation is more pronounced in patients who received intranasal immunization.

The Special Master's discussion of these studies is fairly read to conclude that, while currently available studies have not found evidence that the flu vaccination causes Bell's palsy, researchers have deemed further investigation into this possibility worthwhile based on the evidence that flu vaccination is correlated with an increased risk of Bell's palsy. The Special Master did not mischaracterize these studies when she said they "hypothesized an immune inflammatory response mechanism to be at play." *Entitlement Ruling*, 2022 WL 3369716, at *28. Specifically, because innate and adaptive immune responses are necessarily intertwined, the Special Master reasonably attributed some probative value to the Zhou study even though it implicated an adaptive immune response. The Special Master's reliance on these studies does not render arbitrary and capricious her conclusion that petitioner's innate immune causal mechanism was a sound and reliable theory because, as she recognized, petitioners can satisfy their burden of proof without "supportive epidemiological evidence." *Id.*

B. Logical sequence of cause and effect ruling

Next, under *Althen* prong two, the Special Master found petitioner adequately established "a logical sequence of cause and effect showing that his vaccination was the cause of his Bell's palsy." *Entitlement Ruling*, 2022 WL 3369716, at *28. She found that Mr. Sturdevant's clinical course is consistent with Bell's palsy as well as the petitioner's proposed causal mechanism. *Id.* at *29. The Special Master found the lack of evidence that Mr. Sturdevant suffered injection site swelling or a systemic immune response unproblematic because "it is not unusual for there to be an absence of records noting swollen parotid glands or swollen lymph nodes" given petitioner's physical characteristics. *Id.* The Special Master specifically noted that "petitioner's body stature," sleep apnea, chronic nasal obstruction, and allergic rhinitis could explain why Dr. Depner did not note any signs of swollen lymph nodes on November 5, 2015. *Id.*

The Special Master rejected respondent's argument that Mr. Sturdevant's Bell's palsy was caused by a herpes virus. She reasoned that there was "no evidence that petitioner ever had the herpes virus . . . [n]or did any treating physician opine that petitioner's Bell's palsy was caused by a herpes virus." *Entitlement Ruling*, 2022 WL 3369716, at *29. She found evidence that Mr. Sturdevant improved on antivirals did not support respondent's alternative causal theory because "Dr. Chaudhry conceded that . . . petitioner could have improved on his own" and because petitioner's treatment also included an anti-inflammatory drug that could have independently accounted for his improvement. *Id.*

Respondent contends that "the Special Master's finding that petitioner established a logical sequence of cause and effect under *Althen* prong two lacks an evidentiary basis." Resp't's Mem. at 15. The government points to the lack of evidence of inflammation, noting "petitioner's physical examination one day post-onset showed petitioner's neck was normal to inspection and palpation with no masses appreciated, he had a normal thyroid, and no visible regional lymphadenopathy." *Id.* It also focuses on the lack of evidence of a reaction at the vaccination site, much less a reaction that would "exceed the local environment and enter systemic circulation, as would be required to reach the facial nerve and cause Bell's palsy." *Id.*; *see also* Review Hr'g Tr. 11:1-10 (explaining distal consequences or reactions to systemic inflammation would not occur "in the absence of both local signs of inflammation" at the vaccination site and "systemic signs of inflammation"). Features of Mr. Sturdevant's physique

may explain why this evidence was not detected, but they do not provide evidence of a swollen lymph node. Review Hr'g Tr. 34:5-16.

Petitioner counters that the Special Master rationally found probative Dr. Gershwin's opinions addressing the causal sequence and the absence of medical records regarding injection site inflammation. Pet'r's Resp. at 18-19. Petitioner identifies passages where the Special Master explains why Mr. Sturdevant's stature could account for why no inflammation was noted in his medical record. *Id.* Petitioner also argues no evidence supported respondent's alternative causal theory. *Id.* at 19-20.

The Special Master's determination that petitioner provided preponderant evidence of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury" is neither arbitrary nor capricious. *Boatmon*, 941 F.3d at 1354 (quoting *Althen*, 418 F.3d at 1278). Perhaps the strongest evidence petitioner presented is his treating physician's statement that "[i]t is conceivable that the flu vaccine precipitated [petitioner's Bell's palsy]." *Entitlement Ruling*, 2022 WL 3369716, at *29 (quoting Pet'r's Ex. 26 at 19). Indeed, "[t]he medical records and opinions of treating physicians are 'quite probative' because 'treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Mondello v. Sec'y of Dep't of Health & Hum. Servs.*, 132 Fed. Cl. 316, 323 (2017) (quoting *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006)). Next, the Special Master's decision to credit Dr. Gershwin's opinion that Mr. Sturdevant's stature and medical history explained the "absence of records noting swollen parotid glands or swollen lymph nodes" is reasonable because Dr. Gershwin's opinion is supported by petitioner's medical history. *Entitlement Ruling*, 2022 WL 3369716, at *29; *see also* Pet'r's Ex. 3 at 18-19 (documenting petitioner's history of hypertension, allergic rhinitis, obstructive sleep apnea, diabetes, and obesity).

In comparison, respondent provided no evidence that Mr. Sturdevant ever had the herpes virus, a fact essential to respondent's alternative causal theory. *Entitlement Ruling*, 2022 WL 3369716, at *29. Further, the Special Master explained that Mr. Sturdevant's treatment with anti-viral medication did not provide adequate support for respondent's alternative causal theory because he was also provided anti-inflammatory medication that Dr. Chaudhry acknowledged may have independently accounted for Mr. Sturdevant's improvement. *Id.*

Accordingly, the Special Master articulated a rational connection between Dr. Depner's statement, Dr. Gershwin's testimony, and her finding that petitioner provided preponderant evidence of a logical sequence of how his influenza vaccination caused his Bell's palsy. In reaching this finding, she accounted for the lack of evidence of inflammation by pointing to facts about Mr. Sturdevant's stature and medical conditions. The Special Master also rationally found respondent did not provide sufficient evidence to support its alternative causal theory. The Special Master did not err in finding petitioner satisfied *Althen* prong two.

CONCLUSION

Based on the foregoing, respondent's motion for review of the Special Master's July 19, 2022, ruling on entitlement is **DENIED**, and the Special Master's entitlement ruling is **AFFIRMED**. The Clerk is directed to enter judgment in accordance with this opinion.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge